

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

Criminal No. 15-CR-10076-ADB

WILLIAM FACTEAU,
PATRICK FABIAN

Defendants

ORDER ON DEFENDANTS' MOTION FOR A BILL OF PARTICULARS

November 16, 2015

CABELL, U.S.M.J.

The government alleges in an 18 count indictment that the defendants fraudulently inflated the revenues and stock value of their former employer, Acclarent, by selling the Relieva Stratus Microflow Spacer (the "Stratus") with the intent that it be used for an off-label purpose. The indictment charges the defendants among other things with conspiracy (18 U.S.C. § 371), securities fraud (15 U.S.C. §§ 78j(b), 78ff), wire fraud (18 U.S.C. §§ 1343, 1349), and distributing adulterated or misbranded medical devices (21 U.S.C. §§ 331(a), 333(a)(1)-(2), 351, 352). The defendants contend that they need additional clarifying information in order to adequately understand the charges and defend against them, and seek that information through the pending Motion for A Bill of Particulars (Dkt. No. 128). For the reasons discussed below, the motion is DENIED.

I. DISCUSSION

A. Legal Standard

A bill of particulars is not a discovery tool and it should not be used to obtain disclosure of “evidence, witnesses to be offered at trial, or the government’s legal theories.” *United States v. Stryker Biotech, LLC*, No. 09-10330-GAO, 2010 WL 2900684, *3 (D. Mass. Jul. 21, 2010) (citing *United States v. Smith*, 776 F.2d 1104, 1111 (3d Cir.1985)). Rather, its purpose “is to provide the accused with detail of the charges against him where necessary to enable him to prepare his defense, to avoid surprise at trial, and to protect against double jeopardy.” *Id.* (citing *United States v. Paiva*, 892 F.2d 148, 154 (1st Cir.1989)). A motion for a bill of particulars should be granted only where “the charges set forth in the indictment are so general that they fail to inform the defendant of the specific acts of which he is accused.” *United States v. Blumberg*, No. 3:97-CR-119, 1998 WL 136174, *3 (D. Conn. Mar. 11, 1998) (citing *United States v. Torres*, 901 F.2d 205, 234 (2d Cir.)).

Courts deciding requests for bills of particulars thus consider factors such as the complexity of the charges facing a defendant, the amount of detail in the indictment, the nature of the discovery already provided to the defendants, and whether the information sought relates to matters the government will have to prove at trial. *Stryker Biotech, LLC*, 2010 WL 2900684 at *3; *United States v. Saleme*, No. 94-10287, 1997 WL 37530 (D. Mass. Jan. 13, 1997) (granting motion in part because of complexity of allegations); *United States v. Hsia*, 24 F. Supp. 2d 14, 31 (D.D.C. 1998) (denying portion of motion seeking disclosure of all overt acts committed in furtherance of conspiracy because the government does not have the burden at trial of proving all overt acts). A defendant has the burden of showing that further disclosures are needed to prevent prejudicial surprise, or to allow a meaningful opportunity to defend the action.

Stryker Biotech, LLC, 2010 WL 2900684 at *4 (citing *United States v. Rogers*, 617 F. Supp. 1024, 1027 (D. Colo. 1985)). The question for the Court, therefore, “is not whether the information sought would be beneficial to the defendant, but whether it is *necessary* to his defense.” *Blumberg*, 1998 WL 136174 at *3 (emphasis added).

B. The Particular Claims

The defendants seek additional information in four areas, including: 1) the identities of all those alleged to have engaged in criminal conduct or to have been victims of that conduct; 2) the particulars of each false and misleading statement alleged in the indictment; 3) a declaration one way or the other whether the government contends that certain conduct alleged in the indictment constitutes separate crimes; and 4) clarification as to whether each of the “intent” allegations in the indictment refers to subjective or objective intent.

1. Co-Conspirators/Victims

The indictment in several instances alleges that various entities engaged in criminal conduct but in most instances does not identify those entities by name, doing so in a more general way, through terms such as “Acclarent,” “others at Acclarent,” or “Acclarent representatives.” Similarly, the indictment refers to alleged victims not by name but through more general labels such as “physicians,” “hospitals,” “payors,” and “potential investors.” The defendants argue that they need to know the specific identities of these entities in order to be able to understand and defense against the charges. The defendants acknowledge that the government has provided them with a list of approximately 60 unindicted co-conspirators, the names of all the hospitals that purchased the Stratus, and a spreadsheet listing all Stratus sales, among other discovery, but contend that this is inadequate because they would have to comb through some 6 million pages of discovery in order to find the information they would need.

Although the Court appreciates the relatively broad scope of some of the charges –the conspiracy charge, for example, spans five years and encompasses a considerable amount of company activity during that time, it is not persuaded that the defendants will not be able to adequately understand the charges against them or prepare a defense in the absence of additional information from the government.

First, despite the breadth of the indictment and the use of some categorical labels to refer to certain entities, the indictment here is a speaking indictment and it provides a fairly detailed 114 paragraph narrative as a prelude before setting out the counts. Among other things, that prelude provides an overview of the government’s characterization of the alleged fraud scheme, a summary of Acclarent’s history, Acclarent’s alleged strategy for and development and distribution of the Stratus, the defendants’ alleged approval of the Stratus to be sold for a non-approved use, the actual distribution of the Stratus for that non-approved use, the subsequent sale of Acclarent to Ethicon, Ethicon’s instruction to the defendants to stop promoting the Stratus, the defendants’ alleged decision to nonetheless continue promoting the Stratus in order to achieve revenue and bonus targets, and the defendants’ financial compensation as a result of their alleged conduct.

Moreover, each of the specific counts provides additional information such as relevant dates to further place the charges in context. Further still, the government has provided comprehensive discovery, and done so in a manner that allows the defendants to search for information, including business records, grand jury transcripts and memoranda of witness interviews via an electronic index including over 40 metadata fields, a navigation tool the defendants themselves specifically requested.

So, and by way of example, although the indictment alleges in paragraph 122 as part of the conspiracy charge that “Acclarent” employees delivered the Stratus to “physicians” with the intent that it be used for the purpose of delivering Kenalog-40 to the sinuses, the defendants can almost surely identify the individuals involved where the indictment alleges the overt act took place in 2008 and the defendants have in their possession all of the relevant discovery in a readily searchable format which would allow them to search for records and witness statements by time and subject matter.

Requiring the government in this light to identify by name all of the entities implicated in each count would be tantamount to requiring the government to provide the defendants with a detailed roadmap of its case-in-chief. That would undoubtedly be helpful, but it is not required or warranted here. In the Court’s view, the defendants are more than able through the indictment and corresponding discovery to meaningfully understand and investigate the charges they face.

2. Details Regarding Alleged False Statements

The indictment alleges that the defendants engaged in a scheme to defraud, and provides examples of the types of false and misleading statements the defendants are alleged to have made in furtherance of the scheme. The defendants seek the particular details of each allegedly false and misleading statement, including confirmation as to whether the government also contends that that any truthful statements about off-label use were false or misleading.

Although some courts have granted motions seeking details regarding alleged false statements, there is no general rule requiring detailed disclosures in fraud or false statement cases. *United States v. Anderson*, 441 F. Supp. 2d 15 (D.D.C. 2006) (noting that the decision in *United States v. Trie*, 21 F. Supp. 2d 7 (D.D.C. 1998), which the defendants rely upon, was based upon the complexity of the government’s legal theory in that case). Rather, the key question for

the Court is whether more detail regarding the alleged false statements is necessary to prepare a defense. *United States v. Mandell*, 710 F. Supp. 2d 368, 385 (S.D.N.Y. 2010) (indictment sufficient where non-exhaustive list of examples of false statements provided sufficient notice to prepare defense); *United States v. Sourlis*, 953 F. Supp. 568, 579 (D.N.J. 1996) (same).

Here, and for the reasons noted above, the indictment and discovery produced to date are sufficient in the Court's view to give the defendants notice of the nature of the charges against them, to learn which statements or acts the government potentially may seek to use at trial, and to conduct their own investigation in furtherance of their defense. Again, it would unquestionably benefit the defendants if the government were to additionally identify the specific statements and acts it intends to rely upon, but that is not necessary or required here.

3. Import of Certain Allegations

The defendants seek additional information to learn “whether the Indictment alleges that any of the following constitutes a violation of law: (a) any alleged action or communication made by Acclarent or Defendants regarding reimbursement of Stratus; (b) the alleged use or removal of Lund-Mackay scores; and/or (c) any alleged failure to provide warnings or safety information concerning Stratus to potential purchasers.” The government has responded that these allegations are specifically incorporated into each of the counts in the indictment. As the Court understands it, the government has put the defendants on notice that they should be prepared to defend against these allegations. There is thus no need to require the government to provide any further information.

4. Intent/Intended Use

The defendants argue that the indictment repeatedly refers to the defendants' alleged “intent” and the “intended use” of the Stratus, but fails to specify whether these allegations refer

to the defendants’ “objective intent” as defined in 21 C.F.R. § 804.1, or their “subjective” intent in committing a particular fraudulent crime. This matters, the defendant argues, because subjective intent is not relevant for determining whether a device is misbranded or altered. The defendants seek for that reason to learn “which, if any, allegations in the Indictment reference Mr. Facticeau’s and/or Mr. Fabian’s ‘objective intent,’ as defined in 21 C.F.R. § 804.1, and which reference Mr. Facticeau’s and/or Mr. Fabian’s subjective intent regarding the intended use of Stratus,” and whether the government contends that any true “catalog only” sales were unlawful under the government’s theory of prosecution.

To the extent the defendants’ request raises concerns about the type and scope of conduct that can violate section 333(a)(2) and constitute an unlawful distribution of an adulterated or misbranded medical device, and/or what sort of intent is relevant and/or irrelevant in such a case, the Court deems that to be a legal question best raised with the trial court. For purposes of the instant motion, however, the indictment tracks the language of the pertinent statute, which does not distinguish between objective or subjective intent. *See* 21 U.S.C. § 333(a)(2) (“If any person commits such a violation...*with the intent to defraud or mislead . . .*”). Moreover, and as the government asserts, the indictment makes it clear that the government will seek to show the defendants acted with a subjective intent to defraud. As such, the indictment adequately informs the defendants of the nature of the charged conduct and to require more here would force the government to articulate its theory of the case and in the process possibly risk limiting the evidence it can present on this issue at trial.

II. CONCLUSION

For the foregoing reasons, the defendants' Motion for A Bill of Particulars is DENIED.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: November 16, 2015